Page 19, eight lines from the bottom, delete the word –amidolytic" and substitute therefor --serine protease--.

Page 21, after the last paragraph, please add the following paragraph

--The present invention has been described in detail herein and with reference to cited publications. The publications cited are intended to provide the reader with additional information, not deemed essential to patentability. However, all cited publications are herein incorporated by reference in their entirety.--

IN THE ABSTRACT

Please delete the entire Abstract and substitute therefor:

--Stable pharmaceutical preparations containing blood coagulation Factor VII is disclosed. The pharmaceutical preparations containing blood coagulation Factor VII are free of coagulation inhibitors and are stable over a wide range of environmental conditions. Also provided are blood coagulation Factor VII preparations having a minimum activity of 50 Units/mg of protein that contain less than 5% activated blood coagulation Factor VII (Factor VIIa). The blood coagulation Factor VII containing preparations may also contain other blood coagulation factors and are free from detectable transmissible human pathogens.--

IN THE CLAIMS

Please cancel Claims 1 through 19.

Please add new claims 20 through 46 as follows:

--20. A stable blood coagulation factor preparation comprising:

blood coagulation factor VII having a specific protease activity, when activated, of at least 50 Units(U)/mg of total protein wherein in said blood coagulation factor preparation is free from blood coagulation inhibitors and contains less than approximately 5% of activated blood coagulation factor VII (blood coagulation factor VIIa).

21. The stable blood coagulation factor preparation of claim 20 wherein said blood coagulation factor VII has a specific protease activity, when activated, of greater than 100 Units/mg of total protein.

22. The stable blood coagulation factor preparation of claim 20 wherein said blood coagulation factor VII is present in an amount of between approximately 5 U/mL to approximately 5,000 U/mL.

23. The stable blood coagulation factor preparation of claim 20 wherein said preparation is lyophilized.

24. The stable blood coagulation factor preparation of claim 23 wherein said preparation is stable for at least 12 hours after reconstitution.

25. The stable blood coagulation factor preparation of claim 20 wherein said blood coagulation factor VII is a recombinant protein.

26. The stable blood coagulation factor preparation of claim 20 wherein said blood coagulation factor VII is recovered from normal human plasma.

27. The stable blood coagulation factor preparation of claim 26 wherein said blood coagulation factor preparation has no detectable transmissible human pathogens.

28. A method for preparing a stable blood coagulation factor preparation comprising:

absorbing blood coagulation factor VII from a biological material onto a chromatographic substrate;

selectively eluding said absorbed blood coagulation factor VII from said chromatographic substrate using a blood coagulation inhibitor-free elution buffer; and

selecting an eluate having a specific protease activity of at least 50 U/mg of total protein.

29. The method for preparing a stable blood coagulation factor preparation of claim 28 wherein said elution buffer has a pH of between approximately 5.0 to approximately 9.0.

30. The method for preparing a stable blood coagulation factor preparation of claim 29 wherein said elution buffer has a pH of between approximately 6.0 to approximately 7.5.

31. The method for preparing a stable blood coagulation factor preparation of claim 31 wherein said chromatographic substrate is an anion exchange material and said selective elution being performed using a chromatography column and a chromatography column flow rate of at least 0.15 column volumes per minute.

32. The method for preparing a stable blood coagulation factor preparation of claim 31 wherein said flow rate is between approximately 0.17 to 2.0 column volumes per minute.

33. The method for preparing a stable blood coagulation factor preparation of claim 28 wherein said chromatographic substrate is an immunoaffinity column specific for factor VII.

34. The method for preparing a stable blood coagulation factor preparation of claim 28 wherein said chromatographic substrate is a material having hydrophobic groups.

35. The method for preparing a stable blood coagulation factor preparation of claim 28 wherein said chromatographic substrate is a hydrogel.

36. The method for preparing a stable blood coagulation factor preparation of claim 28 wherein said biological material is selected from the group consisting of blood, plasma, a plasma fraction, a cell culture and a cell culture fraction.

37. The method for preparing a stable blood coagulation factor preparation of claim 31 further comprising absorbing said eluate having a specific protease activity of at least 50 U/mg of total protein onto a second chromatographic substrate having hydrophobic groups and selectively eluding said absorbed eluate from said chromatographic substrate having hydrophobic groups.

38. A pharmaceutical preparation made according to claim 28.

39. A pharmaceutical preparation made according to claim 37.

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40. A stable blood coagulation factor preparation comprising:

blood coagulation factor VII having a specific protease activity, when activated, of at least 50 Units(U)/mg of total protein wherein in said blood coagulation factor preparation is

free from blood coagulation inhibitors and contains less than approximately 5% of activated blood coagulation factor VII (blood coagulation factor VIIa);

at least one additional coagulation factor.

41. The stable blood coagulation factor preparation of claim 40 wherein said blood coagulation factor is selected from the group consisting of factor II, factor IX and factor X.

42. A method for preparing a stable blood coagulation factor preparation comprising:

absorbing blood coagulation factor VII from a biological material onto an anionic chromatographic column;

selectively eluding said absorbed blood coagulation factor VII from said chromatographic column at a flow rate of between approximately 0.17 to 2.0 column volumes per minute using a blood coagulation inhibitor-free elution buffer having a pH of between approximately 6.0 to 7.5; and

selecting an eluate having a specific protease activity of at least 50 U/mg of total protein.

43. The method for preparing a stable blood coagulation factor preparation of claim 42 wherein said biological material is selected from the group consisting of blood, plasma, a plasma fraction, a cell culture and a cell culture fraction.

44. The method for preparing a stable blood coagulation factor preparation of claim 42 further comprising absorbing said eluate having a specific protease activity of at least 50 U/mg of total protein onto a second chromatographic substrate having hydrophobic groups and selectively eluding said absorbed eluate from said chromatographic substrate having hydrophobic groups.

45. A pharmaceutical preparation made according to claim 42.

46. A pharmaceutical preparation made according to claim 44.--